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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
1614	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/833,257	Applicant(s) BUCHANAN ET AL.	
	Examiner Brian S Kwon	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,12-23,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,12-23,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application

1. By amendment filed December 20, 2002, Claim 24 has been cancelled and Claims 10, 12-23 and 25-26 have been amended. Claims 10, 12-23 and 25-26 are currently pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 10 and 12-13 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing endogenous 13-HODE synthesis decrease induced by omega-3 fatty acids in a subject in need thereof, does not reasonably provide enablement for "preventing the inhibition of endogenous 13-HODE synthesis which may occur when omega-3 fatty acids...". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification (Figure 1 and 1A) discloses the comparison data showing the increase in 13-HODE synthesis in rabbits treated with 13-HODE suspended in corn oil vs. 13-HODE suspended in ethyl-EPA. The specification discloses that 13-HODE synthesis in 13-HODE suspended in ethyl-EPA is somewhat lower at all treatment levels compared to the treatment with 13-HODE suspended in corn oil (page 28, line 26 thru page 29, line 1). The specification states that the lower 13-HODE synthesis levels in the ethyl-EPA treated group reflect a suppression of

endogenous 13-HODE synthesis as described by Miller and Ziboh (page 29, lines 3-5). The specification provides sufficient evidence showing the efficacy of using exogenous administration of 13-HODE in reducing omega-3 fatty acids (e.g., ethyl-EPA) induced 13-HODE synthesis decrease. However, the specification fails to provide sufficient amount of direction or guidance in the instant claimed method of the prophylactic use.

If the claimed method is enabled, 13-HODE synthesis in ethyl-EPA treated group should be identical to the treatment group with 13-HODE suspended in corn oil since the administration of exogenous 13-HODE would completely prevent omega-3 fatty acids (e.g., ethyl-EPA) induced 13-HODE synthesis decrease. However, Figure 1 and 1A do not support for such prophylactic use.

The lack of significant guidance from the specification or prior art (most relevant prior art: Miller and Ziboh) with regard to completely preventing the inhibition of omega-3 fatty acids (e.g., ethyl-EPA) induced 13-HODE synthesis decrease with the administration of exogenous 13-HODE makes practicing the claimed invention unpredictable in terms of the prophylactic use. Further, in view of nature of the invention, the amount of guidance present in the specification, state of the prior art and the predictability of the art, it would take undue trials and errors to practice the claimed invention.

For examination purposes, the "preventing the inhibition of 13-HODE synthesis..." is interpreted as "reducing omega-3 fatty acids induced 13-HODE synthesis decrease...".

Attention is directed to In re Wands, 8 USPQ 1400 (CAFC 1988) at 1404 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure

would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls) at 547 the court recited eight factors:

1) the quality of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working example,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 10 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It appears in view the instant specification that the claimed composition is administered in the specific dosage range (or the effective dosage amount) to reduce "omega-3 fatty acids induced 13-HODE synthesis decrease...". However, the claim 10 appears to omit an essential feature of the invention and is consequently unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 14-15, 18-20 and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Carlsson et al. (WO 99/44585).

This rejection is analogous to the original rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 10, 12-13 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (J Invest Dermatol, 1990, 94:353-358).

This rejection is analogous to the original rejection.

7. Claims 16-17 and 21-22 are rejected under 35 USC 103(a) as being unpatentable over Streber (US 5102912) in view of Carlsson et al. (WO 99/44585).

This rejection is analogous to the original rejection.

Response to Arguments

8. Applicant's arguments filed December 20, 2002 have been fully considered but they are not persuasive.

Applicant's argument takes position (with respect to 35 USC 102(a) rejection) that (i) nowhere do Carlsson et al. raise or address the problems of oral formulations of 13-HODE (page 5, para. 3, lines 2-3); and (ii) nowhere do Carlsson et al. discuss or address the issue of providing 13-HODE and omega-3 fatty acids in the same formulation. This argument is not persuasive since both the prior art composition and the instantly claimed composition are drawn to the same composition comprising 13-HODE, carrier (e.g., evening primrose oil), ascorbyl palmitate and additives (e.g., thickener, emulsifier, preservatives). Since claims 19 and 20 are not limited to isolated or purified forms of fatty acids, the referenced composition containing Evening Primrose

oil which contains gamma linolenic acid (GLA) and linolenic acid (LA) anticipates the claimed composition.

Applicant's argument takes position (with respect to 35 USC 103(a) rejection over Miller et al.) that nowhere does the Examiner provide logical reasoning as to why one of ordinary skill in the would combine 13-HODE with omega-3 fatty acids when oral administration of omega-3 fatty acids have been found to inhibit endogeneous 13-HODE synthesis. As also acknowledged by Applicants, the clinical value of omega-3 fatty acids, namely EPA and DHA, are well known (page 19, lines 23-24). Therefore, one having ordinary skill in the art would have expected that the co-administration of 13-HODE with omega-3 fatty acid (e.g., EPA and DHA) would be advantageous over the omega-3 fatty acid alone. One having ordinary skill in the art would have expected that the administration of the omega-3 fatty acid with 13-HODE would enhance the pharmacological activity of the omega-3 fatty acid by compensating for any suppression of endogenous 13-HODE synthesis with exogenous 13-HODE. Further, one having ordinary skill in the art would have expected that the oral administration of 13-HODE would be effective in reversing the suppression of 13-HODE synthesis as comparable to the topical administration since the modulation of endogenous 13-HODE synthesis is involved. One having ordinary skill in the art would have been motivated to incorporate 13-HODE into readily available oral omega-3 fatty acid composition, with the reasonable expectation of success, that the combination of the omega-3 fatty acid and 13-HODE would provide enhanced pharmacological activity.

Applicants argument takes position (with respect to 35 USC 103(a) rejection over Streber in view of Carlsson et al.) that the Examiner over-simplifies the problems of administering fatty

acids and does not appreciate the many specific differences there are between each specific type of phospholipids, fatty acids or other lipids. Further, Applicants allege that (i) each specific lipid has its own specific properties which depend on its precise chemical composition and which are not necessarily possessed by other specific lipids; and (ii) the Streber does describe oral formulation but of 9-HODE and not 13-HODE which is a quite different substance with quite different properties. This is spurious argument. Although the specific example of 13-HODE formulation is not disclosed in Streber, one having ordinary skill in the art would readily recognize from Streber (column 3, line 10-46) that 13-HODE (as a preferred hydroxyoctadecadienic acid) can be formulated into various pharmaceutical formulations including tablet, capsule or solution for injection. Unlike applicants argument, the Examiner finds that the selection of 13-HODE among four hydroxyoctadecadienic acid species to derive at the claimed composition would have been apparent to the skilled artisan. Further, the skilled artisan would have expected as taught by Streber that 13-HODE can be prepared in oily material such as triglyceride. It is noted that even if the reference does not address or acknowledge the property, claims to a composition possessing a particular property or characteristic are still properly rejected by a reference to the same composition since the property or characteristic is deemed to be inherent to the composition.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703)308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

FREDERICK KRASS
PRIMARY EXAMINER
GROUP 1600